K063491

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MEDTRONIC Sofamor Danek
T2™ SCEPTOR™ Spinal System 510(k) Summary
November 2006

I. **Company:** Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

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II. **Product Name:** T2™ SCEPTOR™ Spinal System
Classification: MQP

III. **Description:** The Medtronic Sofamor Danek T2™ SCEPTOR™ System is comprised of a set of various angled and non-angled endcleats and end caps which are affixed to the ends of the PYRAMESH-C® implants. These devices serve to grip the inferior and superior end plates, thus allowing for expulsion resistance. The pyramid-shaped openings located along the wall of the PYRAMESH-C® device allows grafting material to be placed inside the hollow core of the device to help achieve a solid fusion.

The device is made from commercially pure titanium or titanium alloy conforming to such voluntary standards as ASTM F67 and ASTM F136 or the ISO equivalents 5832-2 and 5832-3, and is available in various sizes to match the patients' anatomical requirements.

The T2™ SCEPTOR™ device, used in conjunction with the PYRAMESH-C® device, is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine. These systems include the ZPLATE-II™ Anterior Fixation System, the CD HORIZON® Spinal System, the TSRH® Spinal System, the DYNALOK™ CLASSIC Spinal System, and the Laurain DeWald Anterior Fixation System.

IV. **Indications for Use:** The T2™ System The T2™ SCEPTOR™ Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2 SCEPTOR™ Spinal System consists of a series of end caps and endcleats which must be attached to a PYRAMESH-C® device to form a complete construct. The final construct is to be used with supplemental fixation. Specifically, the T2™ SCEPTOR™ device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, DYNALOK™ CLASSIC Spinal System, the

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VANTAGE™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System, or their successors. Additionally, the T2™ SCEPTOR™ device is intended to be used with bone graft.

V. **Substantial Equivalence**: Documentation, including mechanical test results, provided has demonstrated that the T2™ SCEPTOR™ Spinal System is substantially equivalent to similar previously cleared devices such as the VERTE-STACK® Spinal System (K052931, SE 11/16/05 and K060719, SE 04/14/06) as well as the PYRAMESH-C Spinal System (K011406, SE 12/27/01).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
c/o Ms. Christine Scifert
1800 Pyramid Place
Memphis, Tennessee 38132

MAR 0 5 2007

Re: K063491
Trade Name: T2™ SCEPTOR™ Endcleat System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: January 9, 2007
Received: January 11, 2007

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K063491

Device Name: T2™ SCEPTOR™ Spinal System

Indications for Use:

The T2™ SCEPTOR™ Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2 SCEPTOR™ Spinal System consists of a series of end caps and endcleats which must be attached to a PYRAMESH-C® device to form a complete construct. The final construct is to be used with supplemental fixation. Specifically, the T2™ SCEPTOR™ device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System, or their successors. Additionally, the T2™ SCEPTOR™ device is intended to be used with bone graft.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063491